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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,716	10/15/2001	Mark I. Greene	PENN-0786	4425

7590 04/10/2006
Kathleen A. Tyrrell
Licata & Tyrrell
66 E. Main Street
Marlton, NJ 08053

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,716

Applicant(s)

GREENE ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 AND 15-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 8/11/2005 to the Office action has been entered. Claims 1, and 15-29 are pending.

1. Claims 1 and 15-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 15-29 are vague and indefinite because it is unclear whether or not the phrase "the amplified oligonucleotide", "the oligonucleotide" and "the stained oligonucleotide" refers to the RNA produced by RNA amplification since the phrase "oligonucleotide" can be interpreted that it includes DNA. Clarification is required.

Based upon the amendment, it is still not clear whether or not the phrase "the amplified oligonucleotide" is RNA, which is produced by RNA amplification because no method steps describe how the RNA is produced. Clarification is required.

2. In addition the newly amended claim 1 filed 8/11/2005 is missing language "to a monoclonal antibody for the selected epitope, a single chain Fv for the epitope or a constrained epitope specific CDR". Since there is no indication that the language is intentionally deleted, it is unclear if this is a typographical error.

3. Claim 1 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Eberwine et al. (5,922,553, issued 7/13/1999) in view of Chu et al. (5631,129, issued 5/20/1997)

Eberwine et al. disclose a method, which is for detecting a selected protein by immuno aRNA (See column, 2, lines, 37-50). The presence and quantity of labeled RNA transcript is indicative of the amount of selected protein present (See column 4, lines 33-36 and columns 7-8, claims 1-2). In the method a first antibody targeted to the selected protein is immobilized to a solid support. A RNA-promoter driven cDNA sequence is covalently coupled to a second

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antibody, which binds the selected protein (See column 2, lines 37-51). The technique of a RNA synthesis is explicitly disclosed (See column 3, lines 9-24).

Eberwine et al. do not disclose using fluorescent dye to stain the amplified RNA.

Chu et al. disclose a method of detecting of RNA target using a process that, in assuring the target sequence in the amplified product, avoids or at least reduces the presence of low signal to noise ratios and false positive (See column 3, lines 22-28). The disclosure of Chu et al. suggests fluorogenic compounds that bind to RNA, for example ethidium bromide.

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Eberwine et al. by applying fluorescent dye as taught by Chu et al. which binds to RNA for detect molecule expressing a selected epitope in a sample. As indicated by Chu et al. the method avoids or at least reduces the presence of low signal to noise ratios and false positive (See column 3, lines 22-28) which involves using fluorescent dye (See column 13, lines 30-52). It would have been prima facie obvious to carry out the method for detecting molecule expressing a selected epitope in a sample by using fluorescent dye.

Clarification is required.

As mentioned above, it is unclear that the missed language “to a monoclonal antibody for the selected epitope, a single chain Fv for the epitope or a constrained epitope specific CDR” is deleted or is typo mistake. Thus the rejection is maintained.

Allowable Subject Matter

4. Claims 23-29 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
5. The following is a statement of reasons for the indication of allowable subject matter:

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Concerning claims 23-29, no prior art has been found teaching or suggesting the method of quantifying molecules expressing a selected epitope in a sample by applying an immuno-RNA amplification in which the oligonucleotide is attached to a CDR mimetic or engineered CDR.

The closest prior art is the references of Eberwine et al. (US 5,922,553, issued July 13, 1999) in view of Sano et al. (US 5,665,539, issued September 9, 1997). Eberwine et al. disclose an immuno-RNA amplification for the detection of selected protein (See the Abstract). Eberwine et al. do not disclose the epitope detector is an oligonucleotide attached to a CDR mimetic or engineered CDR.

Summary

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung J.T
March 23, 2006


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
3/29/06